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Impact of Medication Access on HgbA1c Levels for the Uninsured with Diabetes Mellitus Type 2

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Abstract

Purpose: The purpose of this project was to determine if not having a prescription patient assistance program (PAP) has an effect on HgbA1c levels in the uninsured with diabetes mellitus type 2 (DM2) enrolled at a community-based free clinic.

Background: If the uninsured patient has no access to a prescription PAP adherence to an evidence-based-practice (EBP) medication regimen could be compromised and result in high glucose levels leading to DM2 sequelae and a fiscal impact on the health care system.

Methods: Subjects, $n = 14$, were uninsured DM2 patients currently enrolled in a free clinic, ages 18 – 64 years. Instrumentation was a custom data extraction checklist approved by three academic and nurse executive experts. Descriptive, retrospective analysis of secondary data was manually extracted from paper records. The Statistical Package for the Social Sciences (SPSS) was used for analysis with Chi-square cross-tabulation test, a Phi score, and a Fisher's Exact test.

Results: No relationship was found between HgbA1c levels and prescription PAP. Even though no relationship was found in the analysis of the small sample several significant secondary findings resulted in quality improvement initiatives: establishment of a DM2 clinical pathway and a DM2 Patient Registry.

Implications: The project led to the creation of a clinical pathway in the form of an algorithm to meet American Diabetes Association (ADA) standards of DM2 care. The pathway was augmented by creation and implementation of a DM2 Patient Registry. Access to a prescription PAP was improved with a tool for increased awareness of possible gaps in EBP treatment modalities such as HgbA1c monitoring according to ADA standards.

Keywords: uninsured health care, glycemic control, diabetes registry, diabetes management, prescription patient assistance programs

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The Affordable Care Act (ACA) brought insurance coverage to millions of people, however, millions more remain without health care and drug coverage (Felder, Palmer, Lai & Mullen, 2011; Majerol, Newkirk, & Garfield, 2015). Approximately 41 million people make up the uninsured population in the United States due to disparities in funding between the ACA and state Medicaid programs (Majerol et al., 2015). Many are employed in low-income jobs without employee insurance benefits and cannot afford the high insurance premium rates (Majerol et al., 2015). Yet, those do not meet state Medicaid requirements for assistance. Additionally, an unknown outcome is the impact from projected insurance premium increases as reported by the Associated Press (2016) claiming increases may range in excess of nine to thirty-seven percent.

Federal, state, and privately funded community health clinics are in place to serve as a health care home for the uninsured population with services free of charge or minimal fees according to income for enrollees (Almufleh et al., 2015). There is a vicious cycle the uninsured become exposed to when there are no adequate resources and access to continuity of care. The result is increased visits to a safety-net emergency department (ED.) Many of the ED encounters are avoidable and occur due to uncontrolled DM2 from lack of preventive care (Kim, Mortensen & Eldridge, 2015). This project focused on the uninsured who have a high incidence of DM2 who sought care at a community-based free clinic.

A disparity exists when a patient receives preventive care but has no resource for prescription medication setting the stage for an ineffective treatment outcome. The patient subsequently presents at the safety-net ED for an uncontrolled condition. The negative impact on unknown future patient outcome and costs to the community is great (Shepherd, Locke,

Zhang and Maihafer, 2013). Majerol et al. (2015) reported non-reimbursed medical care costs for the uninsured in 2013 was in excess of $84 billion dollars. In 2011, according to Cohen, Kirzinger, and Gindi (2013) patients were known to omit prescribed medication dosages or not fill prescriptions for prolonged periods of time due to costs. These shortcomings for the uninsured place them at risk for poor health care outcomes. In the case of DM2 preventive care and maintenance, the inclusion of a medication resource is essential to a healthy outcome.

Background

DM2 is a pathophysiologic dysfunction of the pancreas where the abnormal resistance of target tissues in muscle, fatty tissue, and the liver are resistant to circulating insulin. The result is hyperglycemia. If untreated and not controlled, it can progress to further pancreatic cell dysfunction and destruction. Diagnosis of diabetes in the United States is at an epidemic level with 29.1 million people being diagnosed according to the Center for Disease Control and Prevention (2014). Approximately 95% of that population have DM2. Ahmed and Munir (2015) reported that prolonged uncontrolled HgbA1c levels increase the chance of complications of diabetes over the lifespan. The patient is placed in a higher risk health status and exposed to more complex life threatening pathophysiology to include micro-and macrovascular disease. The resulting morbidity and mortality of the disease progression contribute to a high rate of poor health care outcomes and a high fiscal cost to the health care system (Watanabe and Ney, 2015). Complications from end-organ damage can include vision loss due to retinopathy, heart disease, stroke, kidney failure with resulting nephropathy and neuropathy (Ahmed and Munir, 2015; Hutchison, 2014; Umar-Kamara, 2011). The costs reported by the Centers for Disease Control Prevention (2014) for the year 2012 was "…$245 billion in total medical costs and lost work and wages." The importance of maintenance and control of this glycemic condition is dynamic.

Regular follow-up care and control of DM2 is essential to a healthy outcome. Researchers studying the continuity of care found support for regular preventive care and treatment for DM2 (Franklin, 2014). For the uninsured, challenges can be multifold. The uninsured need a health care home with continuity of care which includes appropriate health care maintenance. Many uninsured utilize community-based free clinics as their health care home. Through use of an EBP plan of care which include monitoring and appropriate pharmaceuticals, DM2 patients can avoid an out of control condition, an unnecessary emergency department visit, and compromised quality of life.

Monitoring glycemic levels at regular intervals can help the primary care provider monitor and evaluate the success of a long-term treatment protocol keeping the patient within a therapeutic range (Ahmed and Munir, 2015). The method for monitoring glycemic levels is the glycosylated hemoglobin (HgbA1c). HgbA1c level, from a pathogenesis perspective, reflects the attachment of a glucose molecule to the N-terminal of the hemoglobin molecule (Test ID: HBA1C Hemoglobin A1c, Blood, 2016). The erythrocyte is exposed to the glucose molecule for its entire lifespan reflecting a mean glucose concentration for the previous eight to twelve weeks. HgbA1c is a standard of practice for evaluating long-term glycemic control. Individuals with high blood glucose levels can have as much as three times higher HgbA1c levels than those who do not have high elevations.

The American Diabetes Association (2016) recommends HgbA1c maintenance level at < 7% to preclude micro-and macrovascular complications in long-term care. Redmon et al. (2014) recommend glycemic control for DM2 patients be maintained < 7% to < 8% and unique to the patient. The ADA recommendations for on-going care include HgbA1c testing twice yearly under controlled conditions and four times a year for those patients with poor control or

who experience a change in their treatment regimens or disease. Elevated HgbA1c levels > 7% are indicative of poor blood glucose control and is the impetus for looking at the extrinsic cause. Poor control can be associated with poor access to prescription medications for the uninsured. Shepherd et al. (2014) report the number of unnecessary urgent care visits increase for those uninsured who already have a propensity toward medication non-compliance. The investigator in this project looked at the lack of access to prescription medications that could effect HgbA1c levels placing the patient at high risk for DM2 sequelae. Patients having no resources for medications cannot benefit from an appropriate treatment plan. Shepherd et al (2014) stated "Patients without an effective health insurance plan and appropriate medication coverage have not only a likelihood of decreased medication adherence but also an increase in the number of visits to EDs for nonurgent care…." (p. 581).

Prescription medication access for the uninsured must be readily available as part of an EBP plan of care to ensure a positive health care outcome. Many of the community primary care clinics, just as the free clinic setting for this project, do not include free medications. Ward, Armbrecht and Lavin (2012) reported that only 50% of DM2 patients meet ADA standards of care. This finding was attributed to an inability for the uninsured to meet drug costs. Hence, the uninsured are more likely to have uncontrolled blood glucose values than the insured population. Shepherd et al. (2014) in a longitudinal, quasi-experimental design study found a strong predictor of better health care outcomes for the uninsured was "…access to stop-gap prescription medications…" when controlling for resources (p. 581). The result of no medication coverage can add to ED visits with increased costs to the health care system.

Patients diagnosed with chronic illness require continuous access to medications for quality health care outcomes (Shepherd et al., 2014). The importance of access to prescription

medications cannot be overstated in the context of maintenance for DM2. Costs of medications can be a key factor leading to poor compliance in preventive care and can result in high HbgA1c levels (Ward et al., 2012). Some commercial pharmaceutical resources such as Walmart, Target, and Walgreens have programs with significant discounts to the uninsured and low-income patients for certain generic medications for DM2. Unfortunately, if the individual is on several different medications and those medications are not on the availability list they must pay out-of-pocket. Some pharmaceutical companies have sponsored programs offering prescription medications at no cost (Felder et al, 2011). When treating the uninsured for DM2, prescription PAPs are an option to consider in their treatment regimen (Ward et al., 2012). A viable predictor for maintenance of a therapeutic HgbA1c level is access to prescription medication.

The purpose of this project was to assess the correlation between prescription PAPs and hemoglobin HgbA1c levels for uninsured DM2 patients enrolled in a community-based free clinic. This project included a descriptive, retrospective chart review of secondary data from health records of enrolled patients with the DM2 diagnosis. Independent variables included demographics of age, gender, and race as well as, income strata and continuity of care evidenced by HgbA1c levels at three-month intervals over a 12-month timeframe.

Problem Statement

The community-based free volunteer medical clinic enrollees are representative of the uninsured population who have a high rate of DM2 diagnoses. Out-of-pocket costs for prescription medications, especially, if there are more than one, can serve as a barrier to the patient's access to medication. If the uninsured patient has no access to a prescription PAP, adherence to an EBP medication regimen could be compromised resulting in an uncontrolled disease process followed by untoward consequences. The uninsured DM2 patient with elevated

HgbA1c and no PAP is a patient at high risk. This inequity must be corrected for better health care outcomes for the patient, as well as potential costs and resource savings for the health care system.

Purpose of the Project

The purpose of this project was to evaluate the correlation between elevated HgbA1c levels and access to a prescription PAP in the uninsured with DM2 enrolled at a community-based free clinic. A positive correlation suggests the need for a process to ensure medication access for the uninsured clinic enrollees.

PICOT

Population – Adults aged 18-64 with diagnosis of DM Type 2 enrolled in a free clinic

Intervention – HgbA1c levels effected by prescription PAP

Comparison – Patients with no PAP compared to those with PAP on clinic PAP file list

Outcome – Effect on HgbA1c levels

Time – Retrospectively over a 12-month timeframe

Research Question

Among uninsured adults ages 18-64 with a diagnosis of DM2 enrolled in a free clinic, are HgbA1c levels effected by having no prescription PAP over a 12-month timeframe?

Literature Review

Focus of the literature review was directed toward the uninsured with DM2, continuity of care in DM2, HgbA1c monitoring in primary care, access to prescription PAPs, the Chronic Care Model (CCM) and DM2 patient registries. These search topics were narrowed to target extrinsic factors effecting the uninsured DM2 patient providing insight to the role of pharmacy and primary care providers, ED usage, socioeconomic impact, social support systems and looking at

the free clinic environment. Meeting ADA guidelines for continuity of care was foremost in the literature highlighting areas of preventive care and structured models to facilitate positive outcomes.

Search engines used for the literature search were CINAHL Complete, Iliad, ProQuest and Cochrane Library and included publications from 2011 to 2016. Keywords for the search were EBP, health care access, uninsured, primary care, HgbA1c, glycemic control, diabetes registry, CCM, diabetes management, prescription access, and ED utilization. There were ample peer-reviewed studies on the topic.

The Uninsured with DM2

A search of the literature for the uninsured with DM2 provided insight to the plight of the uninsured DM2 patients and the complexities of their condition in relation to how they are effected by their socioeconomic status, barriers to care, and psychosocial status. The literature also provided perspectives in attitudes of the uninsured DM2 patient, attitudes of their volunteer providers and significance of access to free primary care clinics for this vulnerable population.

Diabetes is a serious chronic diagnosis that requires an understanding of the long-term ramifications of the disease and ability to meet the socio-economic challenges that it brings. The diabetes diagnosis is compounded for the uninsured and underserved patients who may have low literacy skills and have economic issues. Alternatives to reach underserved populations are essential in meeting their special medical needs. Rodriguez, Campbell, and Kirksey (2013) conducted a quality improvement pilot study to assess the efficacy of a specialized pharmacy sponsored Diabetes Disease Management (DDM) program for an uninsured poor minority population. The authors cited annual national costs for diabetes care as "$306 billion" (p.747).

Rodriguez et al. (2013) utilized an inter-disciplinary collaborative framework to include two pharmacists and a neighborhood community-based clinic with family practice physicians and nurse practitioners. The clinic provided referrals to the pharmacy program which provided discounted prescription medications, guidance to a prescription PAP and diabetes education. The pharmacist diabetes educator consulted with each patient for diet, weight loss, and foot assessments. The pre-and-post intervention participants, $n = 36$, were selected by their respective primary care provider at the clinic. Comparison of the study outcomes showed statistical significance after one DDM visit, "HgbA1c (pre = 8.57%, post 7.44%, $p < 0.05$, triglycerides (pre = 236, post = 15.66, $p < 0.05$), and BMI (pre = 42, post 35.16, $p < 0.05$)" and no significance for high density lipoprotein (p. 749). The authors concluded that the uninsured and underserved populations with diabetes encounter obstacles in keeping appointments and having a regular resource for medications. The collaborative efforts demonstrated collaboration positively contributed to better health care outcomes that could preclude ED visits for uncontrolled conditions.

The status of the ACA and various state Medicaid programs continues to need clarity and direction for the millions that remain uninsured. The ED utilization has received a fair amount of attention from researchers evaluating the impact of the uninsured and factors precipitating their preference for the ED versus a community-based clinic. In a descriptive, pilot cross-sectional survey study by Lozano et al. (2015) examination was made for the motives of uninsured patients seeking ED care and its effect on ED utilization under the ACA. The study used a 32-item survey measurement tool which included 23 questions extrapolated from the Orange County Health Needs Assessment survey tool for characteristics of a convenience sample, $n = 50$. The respondents were uninsured ED patients with subsequent in-patient admissions. The site of the

study was a Level I university teaching hospital in Orange County, California. The authors examined the respondents measured outcomes for Insurance History, Health Care Utilization, Utilization Choices, and Awareness of Resources. Tables illustrated the analytical results for each variable.

Highlights of the results, as reported by Lozano et al. (2015), showed 58.6% of the respondents were previously insured but lost benefits through employment, 48.3% lost coverage of government programs, and 52.4% never had insurance due to their legal status. Of interest, one-third of the respondents reported they could not afford to pay more than $20 per month for insurance with the remainder admitting an inability to pay even less. Health Care Utilization showed 60% of respondents had community clinic resources and reported lifestyle, diet, lack of insurance and stress as perceived reasons for health issues. Utilization Choices resulted in 56% choosing the ED due to a perception of an emergency type condition, 16% opted for the ED because the ED did not require insurance, and 10% thought the ED provided the fastest access to care. Delays in seeking health care were attributed to lack of insurance by 84% of the respondents with 74% asserting no insurance led to their hospital admission and 84% thought their health status would be better with insurance. The authors noted barriers for the uninsured were access to primary care for 54%, access to medications for 36%, and medical supplies for 24%. Additionally, the authors reported over half of the respondents had seen a doctor within six months, one-third had no doctor visits in the last year with over half of the respondents citing costs as a reason. Awareness of Resources showed 42% of respondents had some familiarity with community health centers.

Lozano et al. (2015) concluded that the respondents chose the ED primarily due to a perceived urgency in their condition, clinical complications were exacerbated by delays, and

access to primary care. Other points made included a continued lack of understanding if the ACA was going to improve access to primary care. Chronic conditions without timely access to primary care could result in an increase in ED utilization for avoidable uncontrolled conditions.

Globally, diabetes is growing exponentially with huge impacts on increases in morbidity, mortality, health care costs to patients, and the health care systems of the world. Bird, Lemstra, Rogers and Moraros (2013) reported in their cross-sectional, population-based study, 5.1 million deaths from diabetes with its sequelae and 548 billion dollars in health care dollars. The authors postulated that of the many studies on factors contributing to effects of DM2, most focused on modifiable and non-modifiable risk factors but did not address income as a risk factor. The authors cited a meta-analysis review of socio-economic factors in relation to DM2 illustrating those patients on lower income strata showed a higher incidence of the disease and females had a higher prevalence over males.

Bird et al. (2013) pointed out their primary study purpose was to assess the effect of income on DM2 with a secondary goal of assessing the effect of income on DM2 variables such as hypertension, obesity, and inactivity. The authors conducted their study in a predominantly socio-economically depressed Canadian community with over five interventions spread between the years 2000-2008. The study sample, n = 27,090, of community residents, were randomly surveyed via a digital telephone system. Demographics were male and female, age 20-80 years or more, marital status, culture, household income and education level.

Bird et al. (2013) reported significant findings between household income and DM2 association after conducting a statistical analysis of the data collected. Households with an income of $29,999 or less had a 9.0% association with DM2 while households with an income range of $30,000-$79,999 range had an association with DM2 of 4.3%. The statistical findings of

a 2.3% association with DM2 for households with incomes of $80,000 or greater was even more revealing of the impact income could potentially have on DM2. Other variables identified as DM2 associated disease, hypertension, OR = 1.76, minority culture, 2.17, obesity OR = 1.97, male, OR = 1.76, and inactivity, OR = 1.15. The authors concluded that the study substantiated that the increased incidence of DM2 was inversely related to income. Further research in the area of income effect on diabetes was recommended.

Self-management for the uninsured DM2 patient to achieve a steady state condition is not only impacted by the clinical aspects of care but also by their social support systems. In a qualitative cross-sectional, interview-based study, Madden et al. (2011) compared attributes of the successful self-managed diabetes uninsured patients to those patients that were unsuccessful. The study samples were patients that received care at a federally funded clinic or a community-based free clinic. The authors validated predisposing behavioral risk factors of poor nutrition, lack of exercise, and depression as high among the uninsured. The uninsured DM2 population is associated with disease sequelae and less optimal health outcomes. The authors looked for those factors in self-management that were used by the uninsured resulting in consistently good outcomes over time notwithstanding the socio-economic conditions. Measurement of the HgbA1c levels was accomplished between the two groups that were identified as the successful, $n = 17$ and unsuccessful, $n = 9$. All patients in the study were 18 years of age and older. Criteria for successful were HgbA1c levels < 7% or a 2% improvement within the previous six months. The unsuccessful group was determined to be > 9% or lack of improvement of ≥ 2% over past two months. Any other category levels were deemed ineligible. Results were illustrated in a detailed table.

Statistical analysis showed no significance among demographic variables and HgbA1c levels were significantly lower for the successful group, 8% versus 10%. Significance was found in the successful group having more co-morbid conditions with medians of 3.0 and 2.0 respectfully. Madden et al. (2011) highlighted important contrasts between the two groups. Successful patients more frequently had family members aiding them in their self-management education, had supportive friends, were more likely to follow an EBP plan of care and were more likely to use the internet for disease information. Additionally, successful patients perceived their disease control as closely related to their last HgbA1c as opposed to the unsuccessful patient not reporting accurate tests results. Successful patients were noted as being more motivated in self-management due to a significant health event. Clinicians in the study rated the unsuccessful patients as having more severe conditions and lower disease control than the successful patients, although, the successful group reported more comorbidities.

Madden et al. (2011) noted depression was more prevalent in the unsuccessful group and was consistent with poor glycemic control and recommended screening for depression should be considered for all DM2 patients. Management of DM2 patients should include education classes and group visits to enhance social support which would benefit those patients without adequate support in their disease.

Community-based free clinics or federally funded clinics have served as the safety net for the uninsured in recent years. These clinics have been successful in filling the gap in health care for the uninsured and have been well received by patients and providers. In a descriptive, community-based research study by Kamimura et al. (2014) diabetes attitudes were explored among uninsured DM2 patients and clinic volunteers. This interesting study was based on the knowledge that free clinic patients often do not have the needed resources or exposure to patient

education to avoid barriers to primary preventive care. The authors centered their study on diabetes attitudes between patients and free clinic volunteer staff. Study participants were 18 years or older, could speak and read English. A comparison was made between three groups, diabetic, $n = 81$, non-diabetic, $n = 198$, and volunteers, $n = 105$. A 33 item Diabetes Attitude Scale from the Michigan Diabetes Research and Training Center was used as a valid and reliable measurement tool. Results showed no significance among demographics between the two diabetes groups. Four tables illustrated participant demographics, diabetes attitudes, and predictors of diabetes attitudes among patients. Average volunteer longevity at the clinic was less than one year. Comparison of attitudes showed significant difference among the groups. Diabetic patients and volunteers demonstrated having a higher appreciation for special training and vocalized DM2 as a dynamic health condition, $p = < 0.01$. Diabetic patients and volunteers demonstrated a higher level of psychosocial interest in disease impact and patient autonomy than non-diabetic patients, $p = < 0.05$. Volunteers valued more stringent control than diabetic and non-diabetic groups, $p = 0.01$.

Kamimura et al. (2014) found that diabetic free clinic patients in the study reported more deficits in physical health, mental health, and as having more dysfunction than non-diabetic patients. Diabetes education may be available in a free clinic but may have varied quality due to inconsistent staffing and financial resources of a free clinic. The authors go as far to say that free clinics may be better oriented toward acute care than chronic care due to challenges for continuity of care when relying on volunteer providers. The authors concluded that both diabetic patients and free clinic volunteers held similar positive levels of diabetes attitudes and held a consensus on the benefit of educational programs in the clinic. The researchers suggested future

strategies could include utilization of non-healthcare professional volunteers for diabetes education.

Volunteer-run community-based free clinics are a mainstay for the uninsured DM2 patient and provide quality, patient-centered care, and EBP. Eldakroury, Olivera, Bicki, Martin and De Groot (2013) in an experimental design study determined if DM2 patients being treated in a volunteer clinic for the uninsured received comparable care to insured patients. The researchers used ADA clinical practice guidelines to assess comparable care among free clinics serving the uninsured with diabetes and clinics serving the insured with diabetes. A retrospective chart review for a cohort study, $n = 33$, was conducted for laboratory results including HgbA1c, lipids, urine microalbumin, and creatinine testing. Other factors examined were demographics of age, race, gender, body mass index, HgbA1c tests frequency/appointment dates, smoking, and alcohol use. The retrospective chart review with descriptive analysis showed HgbA1c as 73% with an average $8.4 \pm 2\%$ and was considered adequate by the researchers in comparison to other studies. Also, comparison of all other laboratory results was consistent in meeting ADA standards of diabetic care. The authors noted that diabetes treatment in the free clinic exceeded better outcomes than other studies in their literature review including those clinics not staffed by volunteer providers.

Eldakroury et al. (2013) recommended adherence to established diabetes care guidelines as being essential in precluding untoward events for diabetes patients over their lifespan. Helpful interventions such as an electronic medical record availability in the free clinics offer an opportunity for provider quality control and consistent documentation for thorough chart reviews. This study validates the need and positive outcomes that can be delivered to uninsured diabetic patients by free clinics.

The consensus from these research studies provided a foundation for understanding the socioeconomic nuances of the DM2 uninsured patient. Long-term implications included modifiable and non-modifiable health risks and access to resources which are essential to optimal outcomes. The health care home for the DM2 uninsured must be augmented to assist patients in overcoming obstacles to quality preventive care to preclude unnecessary ED visits.

Continuity of Care

The literature offered ample studies recognizing factors linking the uninsured to unnecessary use of the ED for uncontrolled chronic conditions and recommendations for alleviating the problem. One of the recurring problems reported was a lack of continuity of care for the uninsured with a chronic disease like DM2 who need regular HgbA1c monitoring. The importance of a regular health care home providing on-going primary preventive care is an essential component of quality outcomes for the uninsured DM2 patient. Employing creativity in meeting the unique needs of this vulnerable population make special care modalities highly effective such as the Chronic Care Model (CCM) and a DM2 Patient Care Registry.

A study by Kim et al. (2015) conducted an intervention study with uninsured individuals with chronic conditions who had a history of ED use to examine the impact of linking them with a primary care clinic. Post-intervention results showed evidence that continuity of care was improved for the uninsured with chronic conditions when they were linked to a primary care clinic. A mixed method research study by Akhavan and Tillgren (2015) looked at equity in health care access for the uninsured. The study concluded that staffing should be diverse, providing patients with ample clinic time, and extended business hours to allow for continuity of care. Almufleh et al. (2015) provided a retrospective analysis of factors on the utilization of federally funded health care centers for the uninsured. The researcher reported the uninsured did

not utilize the clinics due to inflexible hours and nuances of a health care system they did not understand.

In a systematic review of the literature on continuity of care by Franklin (2014), various definitions of continuity of care were found. All definitions had a common thread related to the amount of interface between the patient and their provider. The author summarized that no matter the definition the cogent takeaway was an integral association with on-going regular preventive care as being evident. The author examined the rationale for poor outcomes in patients with DM2 and focused the study on continuity of care represented by HgbA1c levels. Eleven articles were reviewed with results showing the effect of HgbA1c level monitoring improving continuity of care and four articles showing no positive effect.

Franklin (2014) cited one randomized control study, (n=259) with a statistical significance ($p = .029$) for electronic patient reminders and a 0.2 % reduction in HgbA1c levels. Another outcome of the systematic review showed a study ($n = 7{,}000$), where the patient seeing a regular provider had statistical significance for HgbA1c ($P < .01$). Negative results were noted on studies involving special diabetes programs. The author cited that studies with negative results may have been influenced by small sample sizes, limited time-frames for studies, and provider preference for different control levels. The overall implications from the study were positive effects from patient reminders for follow-up care, patient satisfaction increases with improved HgbA1c levels and glycemic testing and improves with a regular provider.

Structure in diabetes management plays a key role in the continuity of care for the uninsured DM2 patient. One intervention supported in the literature was the CCM. In a systematic review of the literature, Stellefson, Dipnarine, and Stopka (2013) studied the CCM model tenets to analyze its operational application and efficacy in primary care. Tenets of the

CCM are a health-system organization of health care, self-management support, decision support, delivery system design, clinical information systems and community resources, and policies. The systematic review, $n = 16$, consisted of a variety of study designs, including randomized controlled trials, prospective cohort studies, natural experiments, a qualitative study, and a cross-sectional study. Variables qualitatively evaluated were "…study design, sample size, setting, participant demographics, primary and secondary outcomes measured, data collection instruments used, statistical tests used, and major findings" (p. para 1, under Data Extraction).

Major findings by Stellefson et al. (2013) in their study on the tenets of the CCM, health care was best effected by organizational leadership implementing the CCM model which was evidenced by a decrease in HgbA1c levels over a 12-month timeframe. Psychosocial and clinical outcomes were improved through the use of certified diabetes educators and follow-up telephone calls to assess if diabetes management standards of care were attained. Improvement was also noted in the use of electronic devices and email to broaden communication capabilities. Decision support was augmented by providers receiving in-service training through information technology for an appropriate response to problem areas such as clinical trends and diagnostic results. The researchers reported an improvement among providers in following EBP guidelines for diabetes care. The training was associated with an improvement of patient knowledge as well.

Delivery system design was found highly useful in its application in the primary care clinic setting which effectively used creative avenues to institute ADA guidelines for diabetes self-management education in special programs for diabetes patients (Stellefson et al., 2013). Clinical information systems were found to be a major asset in using patient care registries and electronic medical records for tracking HgbA1c results enabling timely adjustments to individual care plans. Community resources and policies successfully enabled community leaders,

providers, drug companies, and insurance providers to collaborate in support of provider instruction on the use of the CCM. The authors concluded that the CCM in the primary care clinic setting was beneficial to the diabetes patient in their self-management of the disease. The importance of continuity of care in uninsured DM2 patients is integral to primary care concepts of preventive care and can include not only EBP recommended intervals for HgbA1c monitoring but involves the full spectrum of clinical interventions. Use of a structured care model such as the CCM in the primary care setting can also be an asset in optimal health care outcomes.

HgbA1c Monitoring

Observance of HgbA1c levels was well documented as the gold standard by the ADA for appropriately monitoring patients with diabetes mellitus. In a descriptive, cross-sectional study of DM2 patients in Spain by Alonso-Fernandez et al. (2014) continuity of HgbA1c levels for monitoring glycemic control was investigated. The study also aimed to investigate HgbA1c levels and their relationship with length of diagnosis and use of monotherapy and more complex therapy to include two or more drugs and insulin therapy. The random sampling ($n = 443$) was selected from 17 non-random primary care practices in Spain. The authors' investigation was directed 12 months prior to the study.

Alonso-Fernandez et al. (2014) used a custom observational questionnaire survey tool to address demographics, history, drug treatment, HgbA1c monitoring continuity, and HgbA1c values. Among the authors' findings, 16% (95% CI, 12.6-19.4) had no monitoring of A1c levels. Of those who were monitored, 45% (95% CI 40.4-50.5) resulted in good control < 7%, those with levels < 8% at 27.4%. Patients on monotherapy (65.9%) were in the good control range. Approximately 21% of patients receiving insulin therapy were < 7%. Individuals having only one HgbA1c over the study timeframe had no HgbA1c in the past six months. Alonso-Fernandez

et al. (2014) provided an in-depth discussion on possible limitations of the study. The conclusion of the authors was over 50% of the patients were uncontrolled which was conversely related to disease complexity and 33% of those on monotherapy were not at goal. Emphasis was placed on the importance of continuity in monitoring and adherence to clinical guidelines.

Prescription Patient Assistance Program

A variety of prescriptive PAP's has emerged to augment free access to pharmaceuticals through drug manufacturers, retail pharmacies, and private organizations who offer assistance either free of charge or at minimal costs to the patient. The consensus among authors in the literature was PAPs support positive health care outcomes for the uninsured DM2 patient. Consistent access to a medication resource is not only essential for the diabetes condition but is often beneficial for the treatment of diabetes-associated conditions.

In a retrospective cohort study design of consecutive patients with DM2, Ward, Armbrecht, and Lavin (2012) investigated the correlation between HgbA1c percentages and a medication ratio tool, income, and drug costs. Results showed one-third of the study subjects did not fill their prescriptions due to costs. There was no statistically significant relationship between HgbA1c and monthly income. There was a positive relationship between HgbA1c and drug costs, p=0.005, r=0.462. The authors concluded there was significance in the evaluation of HgbA1c control and pharmaceutical effectiveness of the prescribed medication. The recommendation was made for more studies to assess compliance measures.

Shepherd et al. (2014) conducted a longitudinal, quasi-experimental design to identify the feasibility of a stop-gap medication program for the uninsured that provided immediate prescription availability. The study looked at predictors of outcomes according to health behaviors, prescription history, encounter during follow-up care, and demographics. The sample

population was uninsured adults in a community-based clinic. Of particular interest was a statistically significant relationship between stop-gap eligibility and associated ED visits, p=0.004. Chi-square results supported a significant relationship between elevated blood glucose levels and stop-gap eligibility. Interestingly, the benefit of medication samples showed a relationship with the glucose levels. The authors iterated "Access to medication therapy for chronic diseases reduces morbidity and mortality" (p. 579).

Prescription PAPs provide an important resource for the uninsured, but studies assessing their effectiveness was reported as sparse in a study by Felder et al. (2011). The study included thirty-three studies, specific to PAPs, and were reviewed through commercial and gray publications. The researchers reported both positive and negative perceptions of PAPs. The studies described by the authors were not rigorous and were highly limited. Results were a synthesis of the limitations with no clarity on costs comparisons between commercial pharmaceutical programs and PAPs. Inadequate funding for the studies was given as an explanation for the lack of rigorous research on the subject. Future studies were recommended as being needed.

Prescription PAPs are an important resource for the uninsured contributing to a consistent access to medication and improving quality health care outcomes. In a retrospective pre-post, exploratory study, Toulouse and Kodadek (2016) examined DM2 patient outcomes. The setting for the study was a nurse practitioner-staffed two mobile health van (MHV) operation and was part of a larger 26 associated safety-net clinic system in a mid-eastern region of the United States. The MHVs were responsible for the largest distribution of prescribed medications resourced through local and regional pharmaceutical assistance programs for the uninsured.

These programs were developed to secure robust formularies enabled by donated medications from pharmaceutical manufacturers.

Toulouse and Kodadek (2016) searched for a relationship between continuous access to prescribed medications and common clinical indicators to include HgbA1c, low-density lipoprotein (LDL), and both systolic and diastolic blood pressure. The study sample, $n = 65$, was extracted from stored medical record data spanning over a five-year timeframe at three different retrieval sites used by the safety-net clinics. The framework used in the study was the Dahlgren and Whitehead Social Determinants of Health (SDOH) built on an inverted pyramid concept with four levels. Each level, one through four, were oriented to the process, environment, living conditions to include health care, community support, and health behaviors respectfully. The authors conceptualized the framework to their study at each sequential level examining the effect of continuous access, the intervention of the MHV, measurement of the clinical components, and the existing health status of the uninsured population being studied.

Toulouse and Kodadek (2016) analysis showed evidence of comorbidity, 95.4%, with additional medications given for blood pressure and dyslipidemia, 10% received pharmaceutical treatment for depression. The researchers reported post-interventions as improved over the pre-intervention for HgbA1c, LDL, and systolic blood pressure 0.7% ($p = .003$), 13.1 mg/dL ($p = .004$), and 4.5 mmHg ($p = .025$) respectfully. There was no improvement in the diastolic blood pressure from the intervention. The authors concluded that continuous access to medication for the DM2 uninsured had a positive effect on those physiological parameters significant to a controlled disease condition. Control of these parameters was considered consistent with optimal health care outcomes and findings supported other research studies focused on medication access.

DM2 Patient Registry

A method to streamline preventive care access and promote continuity for the DM2 diagnosed patient can be obtained through a diabetes patient registry which has been rated successful by researchers. The use of a patient registry in the management of diabetes patients results in better patient outcomes, meets quality improvement initiatives and has costs savings potential (Han et al., 2016; Wozniak et al., 2015). Han et al. (2016) conducted a practice assessment survey study to research the feasibility of a diabetes registry in meeting a Meaningful Use quality improvement objective, patient reminders. Avoidable ED use and subsequent hospitalization were also included. Secondary data was examined from 50 outpatient practices, DM2 patients, $n = 10{,}809$. Results reported DM2 patients receiving reminders rated higher for compliance of laboratory testing, odds ratio (*OR*), 1.26, $p < 0.01$, a lower usage of avoidable ED use, *OR* 0.76, $p < 0.01$, and a lower rate of avoidable hospitalization, *OR* 0.83, $p < 0.01$. Majerol et al. (2015) in their Kaiser Family Foundation Report documented that the uninsured were less likely to receive consistent preventive care and often suffer the consequences of delayed care.

Morrow et al. (2013) investigated the efficacy of a diabetes patient registry in small and mid-sized primary care practices. The study design was a longitudinal, prospective cohort analysis. The methodology involved evaluation of measurements for HgbA1c, blood pressure, and lipid levels across seven practices, $n = 1{,}212$, patient sample. The intent of the study was to quickly identify critical areas of concern through a patient registry to enable better patient outcomes within the gold standards for diabetes care. Results specific to HgbA1c < 9%, revealed better outcomes with the registry, *OR* 1.43, 95% CI (1.05, 1.31), $p = <0.001$. The authors claim an integral finding was the patient registry tool can uniquely enable primary care practices to

"…locate the entire target population of patients and measure their key care components…" (p. 143).

Diabetes patient registries provide valid data for quality-improvement interventions in the primary care setting. They are highly useful in tracking specific clinical populations with chronic disease conditions such as DM2 and help strategize organizational policy in the care of the DM2 patient. Wozniak et al. (2015) conducted a qualitative, quality-improvement intervention study to identify creation and utility of patient registries in the primary care clinic setting to focus on a specific population of chronic disease in association with improved health care outcomes. The study was part of a quality improvement project called Alberta's Caring for Diabetes. Respondents, $n = 7$, from four primary care networks, included the executive directors and chronic disease managers. The authors used a framework to assess the institution of the project interventions which was based on reach, effectiveness, adoption, implementation, and maintenance (RE-AIM). Samples of the DM2 population were gleaned from existing four primary care network registries. Data collection was accomplished through interviews with the respondents and systematic documentation.

Wozniak et al. (2015), had four themes for measured outcomes: "Varying ability of primary care networks to estimate and identify target populations for usual care…" (p. 579) and maintain registry customization, quality, and exploitation of its use. Major findings of the study concluded that primary care clinics with registries are capable of appropriate feedback to providers and reminding patients of care provisions, in turn, providing a better health care outcome. Emphasis was placed on the importance of data input for the registries which requires marked accuracy and that the data has an impact on public health. Attention was also directed

toward the need for adequate resources to maintain an accurate and updated registry for a quality product.

Interventions to enhance and streamline quality health care delivery to the uninsured DM2 patient aid in the clinical organization providing an opportunity for EBP and offers accountability in the patient care process. Umar-Kamara and Tufts (2011) conducted a pre- and post-intervention retrospective design study examining the effect of providers following recommended gold standards of care for DM2 patients. The before and after quality improvement initiative was based on quality indicators for a national diabetes recognition program. Variables for processes of treatment in a primary care clinic included measurements for HgbA1c, blood pressure, eye exams, smoking status, lipids, and assessments for neuropathies. Results showed, $n = 48$, age, $M = 62.21$ years, female, 64.6%, African-Americans, 56.5%, HgbA1c and blood pressure showed no statistical significance. There was a significant improvement of eye exams, urine microalbumin, and foot exams, which saw increases of 6%, 28% and 48% respectfully. Even though the authors cited limitations in the study due to a small sample size, they concluded that "…use of practice aids such as diabetes flow sheets, guidelines, reminders, standard referral forms can improve the extent to which patients with type 2 diabetes receive recommended monitoring" (p. 533). These adjuncts contribute to better disease outcomes and costs savings to the health care system.

Synthesis of the Evidence

Synthesis of the literature provided the foundation for understanding the complexities the uninsured DM2 patient faces in pursuit of their health care maintenance and maintaining a quality of life. Emphasis was highlighted on modifiable and non-modifiable risks factors, barriers to resources, and the impact of socioeconomic stressors. Socioeconomic stressors can

significantly impact the individual's needs such as affordability of appropriate foodstuffs, transportation, and time off from the job without pay for medical appointments. Other factors can include access to a safe area to exercise, access to prescription medication, and medical supplies for self-monitoring of glucose.

The importance of structured EBP regimens for appropriate monitoring of HgbA1c affording continuity of care for the uninsured DM2 patient was evidenced in the literature as well as the positive attributes of a prescription PAP. Examples of structured processes were illustrated in the CCM and DM2 Patient Registry and were strongly supported in the literature as an important adjunct in long-term preventive care for the uninsured DM2 patient.

The strength of the literature review was available up-to-date quantitative and qualitative research studies which include samples of descriptive, retrospective, cross-sectional and quasi-experimental designs. Documentation was plentiful supporting the use of HgbA1c level in the evaluation of therapeutic levels for DM2 glycemic status. A limitation in the literature was noted as a sparsity of studies identifying factors that contribute to the uncontrolled condition due to poor access to medication for the uninsured population. The literature validated a negative impact related to drug costs on uncontrolled HgbA1c and access to available medications. A logical question would be if an individual has full access to free primary care, is a lack of medication availability a barrier that continues to exist and needs to be addressed for this population?

Theoretical Framework

A change theory framework by Kurt Lewin was used for the project. The theory has three main elements described as unfreezing, moving or transition and refreezing (Moran & Conrad, 2014; Manchester et al, 2014, Mitchell, 2012; Jacelon, Furman, Rea, Macdonald and

Donoghue, 2011). Swanson and Creed (2014) illustrated the three elements in a diagram (see Appendix A). An application of the theory to this project, created by the study's author, is illustrated in Figure 1.

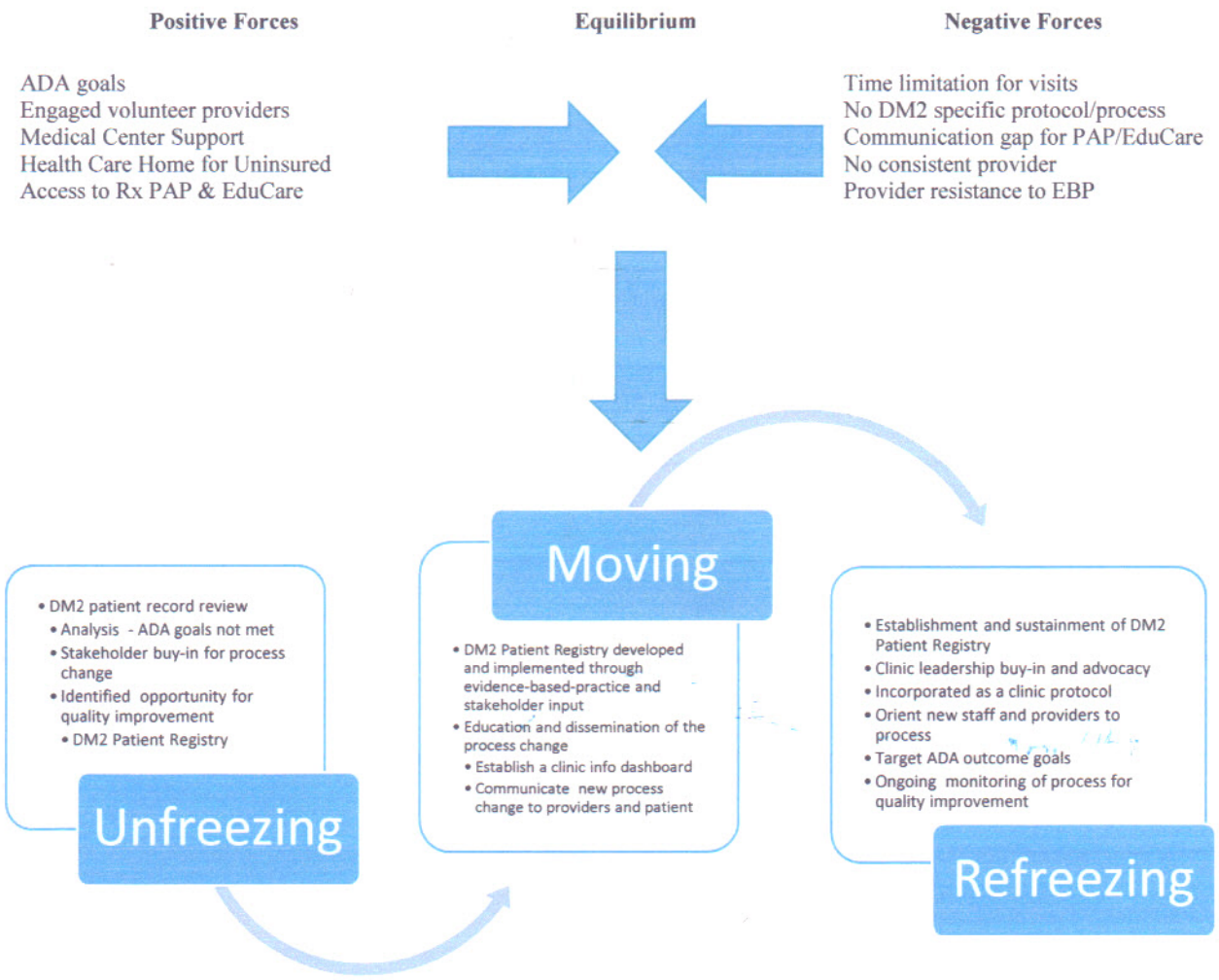

Figure 1. Lewin's Conceptual Change Model Adapted for Uninsured DM2 Patients (Doyle, 2016; Kaminski, 2011)

Kaminski (2011) explains Lewin's theory as including the concept of "force field analysis" (para 1, under Force Field Analysis; Black, 2015) which is the environmental base of the three elements that maintains equilibrium. Kaminski describes the equilibrium between the

elements as either being conducive to change or being a barrier. When there is a disparity between the two, the resolution is accomplished by either changing the status to a positive or changing effect causing the impediment or negative outcome. An in-depth discussion of Lewin's Theory of Planned Change by Shirey (2013) provided a succinct synopsis of the theory's "strengths, limitations, and targeted application" from a humanistic standpoint (p. 69). Shirey iterated the theory's applicability to a variety of scenarios including clinical and managerial situations. This resourceful peer reviewed article elaborated on the key aspects of the theory's three key elements based on the force field analysis concept and those forces described as "...driving…" or "…hindering…" (p. 70).

Forces helpful to change in this project for the free clinic's DM2 care regimen was the consensus by stakeholders to meet ADA goals and their committed interest in patient-centered health care delivery. The clinic offered many quality attributes to include a health care home for the uninsured DM2 patient and ample volunteer participation by highly credentialed providers from the community who were service oriented. A key asset was the diagnostic and patient education support from the local state-of-the-art medical center. Other virtues of clinic services to the DM2 patient included access to a Community Health Works prescription PAP and amenable operational hours for patients with flex schedules.

Forces considered as hindrances varied and included no specific DM2 management protocol or process to ensure continuity of care. There were communication gaps for enrollment in a prescription PAP and patient education through EduCare. Additional hindrances were a limited amount of time for adequate provider assessments, possible provider resistance to an EBP plan of care, possible patient non-compliance and no consistency for the patient to see the same provider at subsequent visits. Other hindrances could include patients with low-income

employment who often work odd shifts with potential conflict in relation to clinic operational hours and may have transportation issues. There was no public transportation in the city where the clinic was located and could thwart efforts to keep scheduled appointments. The uninsured are most likely to have a lower than average educational level and may have a poor understanding of the disease process leading to non-compliance of the treatment plan (Kamimura et al. (2014). The advent of depression which is consistent with chronic illness may also enable non-compliance for medication and follow-up appointments (Madden, 2011).

Utilization of Lewin's theory for its ease of application was illustrated and well documented in the literature. In an exploratory research study by Manchester et al. (2014), Lewin's change model was assessed for the relationships between EBP and their respective organization. The authors applied Lewin's three step model, unfreezing, movement, and refreezing, to two Geriatric Education Centers, supported by federal funds, with a focus on their EBP in relation to a falls risk assessment and their follow-up procedures. The authors suggest there were discrepancies in the EBPs in some proven previous programs indicating inconsistent reliability and cite the reason as a poor theoretical framework for EBP projects. Conclusions of the study involved recognizing that disequilibrium varied with the relevant circumstances such as different operations and capabilities within a functioning department. The authors elaborate on the possibility of using Lewin's theory in combined frameworks for clinical EBP translational projects. The takeaway from the study was the ease of using the Lewin theory and importance of early buy-in by key stakeholders for the long-term viability of the practice.

Force Field Analysis

The force field analysis guided optimization of factors found helpful toward positive change and helped minimize any negative counter factors in pursuit of an optimal change

outcome. In a simpler interpretation of Shirey (2013), you must identify whatever is causing the problem by recognizing the good and bad effectors. Use communication and collaboration to clarify and confirm the circumstances of the situation at hand and educate stakeholders how to reach a positive goal. Implement the positive change process through EBP tools and ensure sustainability of the new process by nurturing its support with positive intervention and periodic re-evaluation.

Unfreezing

The unfreezing was identified in the secondary finding of the study exposing the need to ensure a more consistent process for the uninsured to access prescription medication. Even though there was no significance in the descriptive analysis, $x^2 (1) = .93$, $p = > .05$, $Ø = -.25$, Fischer Exact $p > 0.05$, between HgbA1c and PAP scores, other observations warranted changes to the process. Of the original sample ($n = 28$), only 50% had one HgbA1c result for the 12-month timeframe with an average 3.8 visits to the clinic in the same timeframe. Other data results showed 1.1% (3) of the total sample had no results, yet visits to the clinic varied from four to ten times over the 12 months. Through systematic data collection based on pertinent pre-established evidence-based clinical criteria, an ineffective process in DM2 preventive care was found. A disparity in equilibrium was recognized. This was identified as an opportunity for quality improvement and an initiative for a change in the DM2 preventive care process.

Unfreezing was illustrated in the evaluation of the clinic enrollee with DM2 through documentation in the continuity of care for monitoring the patient's HgbA1c levels and ensuring their enrollment in a prescription PAP. The systematic review of each DM2 patient's record, evaluation, and analysis of the data collected established the need for a change in the DM2 patient care process. Lewin's element of unfreezing targets areas in need of a process change

(Kaminski, 2011). Results of the findings identified a need for a quality improvement initiative to change the process in DM2 preventive care. Results of the statistical analysis were shared with the clinic stakeholders and consensus to meet ADA DM2 goals was agreed upon. A tool to create an effective process was the development of a DM2 protocol, the DM2 Management Algorithm (see Appendix B), based on ADA 2016 guidelines. To operationalize the protocol, the DM2 Patient Registry (see Appendix C), was developed by the author which offered a quick reference for providers enabling a consistent preventive care trajectory for the DM2 patient. The DM2 Patient Registry format provided a method of tracking timelines for obtaining critical laboratory results and scheduled examinations useful for a quick look concept by the respective provider to aid in the continuity of care for the patient. It also enabled documentation of a PAP and patient education or EduCare. Communication on intricacies and operationalization of the protocol algorithm and registry with critical stakeholders brought consensus for instituting a DM2 Patient Registry to improve the quality of health care delivery to the uninsured DM2 patient.

Moving

The moving element guided the process needed to make the recommended change to the health care delivery for the patient. The process to make the change was the development of a DM2 Patient Registry to ensure DM2 management of risk factors according to the ADA. Of importance, was the input and collaboration of key stakeholders that pinpointed specific needs of the uninsured DM2 population in conjunction with ADA guidelines and pledged support for initiation and sustainment for a DM2 Patient Registry. Additional input was solicited from the stakeholders and was added to components of the registry. Representative stakeholders in the process included the clinic's administrator, medical director, a volunteer endocrinologist, and a family nurse practitioner. Having the stakeholders as part of the change process enhanced buy-in

and communication for education and dissemination of the project to other clinic providers. Collaboration between the provider and the patient was also recognized as essential to ensuring the patient is educated on components of the registry and the patient's responsibility in keeping regular clinic appointments.

Since the clinic was relatively small, the mechanics of communication relied upon verbal encounter with clinic providers by the clinic administrator and medical director. Communication was augmented by a paper dashboard explaining the new process and its rationale. A dashboard is a simple working display showing trends from various data resources for quick information updates (Sewell, 2016). Even though dashboards are normally thought of as a product of information systems, the paper version provides a workaround until the clinic has the electronic capability. The paper dashboard type flyer was displayed in close proximity to the provider workstation for ease of viewing. As new volunteer providers and ancillary staff join the clinic sustainment of the process will be briefed to the providers during orientation to the clinic (Kaminski, 2011).

Refreezing

The refreezing element was guided by the establishment of the new clinical protocol tool and a DM2 Patient Registry, for each enrolled DM2 patient. Each DM2 patient record received an annotated copy of the DM2 Patient Registry form. The registry offered EBP guidance and accountability for the new process to ensure access to a PAP enrollment, EduCare, and chronic DM2 diagnosis managed in accordance with EBP gold standards. Efforts to sustain the change included incorporation of the registry as a clinic protocol with staff and providers oriented to the new process or change. According to Shirey (2013), leadership in advocating for positive re-enforcement of the change was needed to sustain the new "norm" (p. 70). Stakeholder buy-in

was essential with on-going support through initiatives such as the implementation of electronic medical record or electronic health record capability when possible and automated patient reminders. Scheduled monitoring and dissemination of clinic DM2 statistical outcomes to providers and staff may help to maintain focus on the changed process. In the future, annual re-assessment of the new practice process should be assessed for positive outcomes with review and revision as indicated by the findings (Sutherland, 2013).

Methodology

The Methodology section was oriented to answering the project purpose which included a subset of the clinic patient population, DM2 patients, and the impact to their HgbA1c level if they had no prescription patient assistance program. The lone investigator created a checklist data extraction tool for raw patient record data which was implemented according to pre-established parameters for inclusion and exclusion criteria for the records.

Population

This project included a descriptive, retrospective chart review of secondary data from paper health records for a clinic population, $n = 177$, uninsured clinic enrollees. Due to the minimal ethical risk of this project, an institutional review board (IRB) was not required by the Board of Directors for the clinic and was categorized as exempt by the Georgia College and State University IRB.

Setting

The setting was a free primary care medical clinic located in a middle Georgia county which offers primary, non-emergent medical care on an appointment-only basis. The mission of the clinic was to provide care to the county's underserved uninsured. The clinic was staffed with approximately 48 volunteer physician and nurse practitioner providers. The providers were

associated with private practice or were in a retired status and most often practiced in primary care and internal medicine. Some specialist donated time to the clinic, such as cardiologist and endocrinologist. There were three paid administrative staff who worked at the clinic in a full-time capacity. The providers voluntarily signed-up for their availability times to treat patients during regular clinic operating hours. Since the volunteer providers randomly designate a time at the clinic patients may not always see the same provider. To qualify for services individuals must live in the county, be between ages 18-64, be employed or his or her spouse must be employed, must be uninsured, and the household income must be 200 percent of poverty level or less. Household size for income was provided according to monetarily defined levels based on one through eight members in the household (Houston Healthcare, 2016).

Tools

A checklist for retrospective data extraction (see Appendix D) was created and utilized by the lone investigator (PI). The Andersen Behavior Model of Health Services Use was used as a reference to develop a template for a retrospective clinical data extraction form (Shepherd et al., 2014). The model was a tool enabling prediction of how predisposing factors influence clinical outcomes for uninsured patients with chronic conditions requiring treatment.

Intervention and Data Collection

Data extraction followed the checklist format with raw data applied to the Statistical Package for the Social Sciences (SPSS), version 23 software to develop a project database. The internal validity and reliability of the data extraction were supported by the standardized instrument/checklist applied to each record reviewed by the lone PI.

The patient's clinic registration number was cross-referenced with a numerical code to protect personal health information. The dependent variable, HgbA1c, was examined for levels at or below 7% which was used as the threshold defining a controlled condition. A HgbA1c level

> 7% was considered above the threshold and defined as uncontrolled. The number of HgbA1c tests with their respective date and level obtained during the project period was recorded to represent the continuity of care. Independent variables included, demographics of gender, age, race, income strata according to number of members in the household, the number of total clinic visits by date, prescription history and documentation for participation in a prescription PAP. The resulting database was cross-match with the clinic prescription PAP files to validate participation.

No recruitment of investigators was indicated. The author was the lone investigator. A convenience sample was used for all DM2 patients identified in the data search. The timeframe for data extracted was 12 months previous to the start of the data collection intervention for the project, 1 January 2015 to 1 January 2016. Inclusion criteria were all enrolled clinic patients with a previously documented diagnosis of DM2. Patients must have had at least two clinic visits prior to the data search with at least one prescription for DM2 treatment and two HgbA1c laboratory results. One result from the initial visit and one at the three-month or six-month interval if they were a new patient. An associated secondary outcome of the project was the development and implementation, by the author, of a DM2 Patient Management Algorithm and a DM2 Patient Registry (see Appendices B and C).

Results

Results focused on data analysis for the demographics of the project subjects, the relationship between HgbA1c and prescription PAP, and the possible correlation between the independent variables. The data analysis outcomes identified areas for quality improvement and future recommendations for an EBP plan of care for the uninsured DM2 patient. The data analysis lead to the creation of a new clinic tool for ongoing DM2 patient management.

Data Analysis

The Statistical Package for the Social Sciences, version 23 (SPSS) was used for the statistical analysis of the project. A review of clinic enrollee paper records ($N = 177$) revealed 16% of patient records ($n = 28$) with a diagnosis of DM2. All DM2 records served as a convenience sample. Each record was reviewed according to the data extraction form checklist. Two consecutive reviews of the 28 records were accomplished for data accuracy. Records meeting the project criteria ($n = 14$) were 50% of the DM2 population for the clinic. The remaining 50%, ($n = 14$), of the DM2 records did not meet the established project criteria and were excluded. The sample size was determined per an online sample size calculator by Raosoft, Inc. (2004) with a recommendation of 14 samples for the study. Although the excluded records were not statistically analyzed they provided some insight for further study. Records of new patients or existing patients with a new diagnosis of DM2 comprised 2% (6) of the records. Patient records with no HgbA1c results comprised 1.1% (3) but had four, five and ten clinic visits respectively over the project timeframe. Patient records with one HgbA1c result comprised 1.8% (5) of the DM2 records and averaged 3.8 clinic visits per patient over the 12-month timeframe.

Descriptive statistics were used to analyze demographics of the 14 patients meeting criteria, Table 1, females, $n = 9$, 64.3% and males, $n = 5$, 35.7%. All the records meeting content of the criteria fell into the 40-64 age group. Caucasians were 64.3% of the sample, African-Americans were 21.4%, and Asians were 14.3%. Income range results included 50% of patients in the $27,380 bracket, 28% of the patients were in the $20,240 income bracket, and 21.4% were in the $34,340 bracket.

Table 1

Demographics of study subjects (n = 14)

Demographic	*n*	%
Gender		
Male	5	35.7
Female	9	64.3
Age		
18-39	0	0.0
40-64	14	100
Race		
African American	3	21.4
Asian	2	14.3
Caucasian	9	64.3
Hispanic	0	0.0
Annual Household Income		
$20,240	4	28.6
$27,380	7	50.0
$34,340	3	21.4
$41,300	0	0.0
$48,260	0	0.0
$55,220	0	0.0
$62,180	0	0.0
$69,140	0	0.0

Descriptive statistical analysis, with $a = .05$, was established for a Crosstabulation Chi-Square Test and a Phi score used for correlation of the two categorical parameters of HgbA1c and PAP, $x^2(1) = .93$, $p = > .05$, $Ø = -.25$. No significance was found in this project for a relationship between HgbA1c levels and prescription PAP. The Phi score was used to demonstrate a weak relationship effect size. The Fisher's Exact Test, $p > 0.05$, was employed to adjust for an expected frequency less than 5 which violates assumptions of the Chi-Square Test.

Spearman's Rho, with an $a = .01$, was used to measure the statistical relationship between ordinal to ordinal variables: HgbA1c and Income Strata, Sig, $r = -.74$, $p = < 0.01$; HgbA1c and race, Sig, $r = .63$, $p < 0.05$. HgbA1c levels and number of HgbA1c tests and clinic visits over one year which were representative of the continuity of care were not significant, $r = .24$, $p > .01$,

$r = -.3$, $p = > 0.05$, respectfully. There were no significant correlations for gender or age. Raw data for HgbA1c levels, $n = 14$, $M = 7.09$, $SD = 1.18$, were noted over the 12-month timeframe.

Discussion

Analysis of the HgbA1c and prescription PAP correlation was inconsistent with other studies showing a positive correlation in the literature and was most likely a result of the small sample number which may have effected the statistical outcome. A definitive answer to the research question, are HgbA1c levels effected by having no prescription PAP, was not obtained due to the small sample. Although, the descriptive data, importantly, reflected areas for further investigation and identified opportunities for improved quality of care. There was an opportunity for improvement identified to ensure 2.9% (8) of those without HgbA1c or only one HgbA1c receive an EBP plan of care which could be managed through a DM2 Patient Registry. Of clinical interest was 75% of those patients meeting criteria were at or below goal, < 7%, with no PAP. Those above or not meeting goal, HgbA1c > 7%, with PAP and without PAP were both at 50% respectively. These variables should be assessed again 12 months after implementation of the DM2 Patient Registry.

Frequency distributions exhibited three patients were not meeting goals that were without a PAP and three patients with PAP were not meeting goals. Further investigation should look at factors possibly effecting the three patients with PAP but still not in controlled status. Future questions should be oriented toward medication compliance, patient education on self-management, and ensuring an EBP plan of care. No significant association was made between the number of HgbA1c tests representing the continuity of care with a minimum of two tests and a maximum of four, $n = 14$, $M = 2.64$, $SD = .63$, over the 12-month study period. HgbA1c and clinic visits revealed no correlation as well with minimum visits of two and a maximum of six,

$n = 14$, $M = 3.42$, $SD = 1.22$. A positive relationship was noted between HgA1c and Income Strata, $r = -.74$, $p < .01$, $M = 1.92$, $SD = .73$, showing $27,380 annually, with a two-member household and was consistent with other research studies. The positive correlation may indicate the advantage of a support system in the home and the advantage of having a family member or friend in the home with first-hand knowledge of the DM2 disease process as cited by Madden et al. (20ll). There was a correlation between HgbA1c and race, $r = .63$, $p = < 0.1$ with Caucasians and is not consistent with most of the literature which identifies minorities with higher rates of DM2. The result was most likely due to the small sample. The aggregate results for HgbA1c levels, $n = 14$, $M = 7.09$, $SD = 1.18$, which included an adjustment for one outlier score of 10.4%, and supports the need for a structured process in the continuity of care to obtain better control < 7%.

Conclusions

In conclusion, the research project did not provide evidence that HgbA1c levels were effected by having no prescription PAP over the study's 12-month timeframe. The study did identify areas for quality improvement and gave impetus for further study on the topic. The literature served as a reminder of the significance of socioeconomic status of patients and the cascading effects of low income on an uninsured DM2 patient. The patient must be looked at from a logistic perspective with tools of engagement used to remedy any shortcomings in health care delivery to them. Addressing and ameliorating barriers for the uninsured DM2 patient is balanced on awareness and understanding of barriers such as poor access to prescription medication, variable costs and lack of support systems. The uninsured rely on EBP quality health care through their community free clinics to help overcome these barriers. The DM2 patient preventive care needs may not always be complex but are detailed and in need of a dedicated

coordination of events. The coordination can be attained through implementation of helpful proven tools such as the CCM and the application of a DM2 Patient Registry. The tool best suited for the free clinic in this project was the DM2 Patient Registry. The CCM, although, a proven tool in support of DM2 self-management, is predicated on having electronic medical record capability which precludes its use by the clinic currently but should be a future goal.

Application of a DM2 Patient Registry can facilitate the needed clinical coordination for preventive care to ensure an optimal health care outcome for the DM2 uninsured enrollee. An example of a DM2 Patient Registry is offered (see Appendix B). The registry is composed of the essential preventive care events required for the DM2 patient annually to ensure a trajectory towards positive health care outcomes. The registry was created by the project researcher in accordance with ADA 2016 goals for DM2. It was developed in consideration of the input from the volunteer medical clinic's stakeholders to include the administrative director, the medical director, the volunteer endocrinologists and the nurse practitioner. The lone investigator created a clinical protocol, the DM2 Management Algorithm (see Appendix D), in compliance with ADA standards of care. The DM2 Patient Registry augments the protocol and serves as a work sheet quick DM2 reference tool for providers.

The registry tool is a paper format due to the clinic being on a paper record system until an electronic medical record can be implemented. The paper registry form was applied to the paper record as a top sheet over the patient visit form. This places the form in a location for eye contact as an attention method and ease of use for the provider. The form can be annotated by the provider as indicated over a one-year timeframe for surveillance continuity. At the end of the year, a new form can be added by the administrative staff for the following year. The form becomes part of the patient's permanent record and offers any provider a quick look at the

patient's status and serves as a clinical guide to a coordinated plan of care. The registry form can be annotated on an Excel spreadsheet for administrative ease and archiving of data. In the event of an electronic medical record, appropriate software can accommodate the DM2 registry and include automatic printouts for due dates and appointment reminders to the DM2 patients.

The project garnered lessons learned from the data sample that some patients, even though having multiple regular visits, may not be on an EBP regimen which includes the requisite HgbA1c monitoring intervals according to their control status. Additionally, a process to ensure all patients are contacted for enrollment and participation in the prescription PAP at their initial visit or DM2 diagnosis should be employed. This can be accommodated through the use of the DM2 Patient Registry and the DM2 Patient Management Algorithm.

Implications

The implications for the project are identifying the uninsured with a DM2 diagnosis that needs to be enrolled in the clinic prescription PAP and employ additional therapeutic treatment modalities as indicated in-line with ADA standards. Consideration in primary care delivery to the uninsured DM2 enrollees of the clinic should incorporate factors identified in the project to address any gaps in continuity of care. The predominately 40-64 age group with low-income may have a higher level of need for prescription assistance due to polypharmacy in which all medications should be covered. Annual preventive maintenance should include not only exams for lipids and blood chemistry but tracking of eye examinations, foot care, and kidney function tests. These preventive measures are consistent with the American Diabetes Association (2016) guidelines and are applicable globally.

More aggressive monitoring for continuity of care consistent with the gold standard for DM2 may be indicated. It is an opportunity to ensure an EBP plan of care for every uninsured

DM2 patient enrollee. In order to assist with the EBP plan of care a DM2 Management Algorithm, a DM2 Patient Registry, and a DM2 patient database for the clinic was developed and implemented. The intended outcomes provided access to a prescription PAP, an EBP plan of care, an opportunity for improved quality of life for the uninsured, and avoidance of unnecessary ED visits saving health care system assets.

A significant limitation of the project was the small sample size. A future follow-up project on the topic may elect to broaden the project timeframe. When assessing continuity of care for the uninsured DM2 patient, in a community-based free clinic, consideration must be given to the limitations in achieving gold standards of care due to reliance upon volunteer providers and an often unstable population. Conflicted scheduling can be unpredictable due to provider availability, a patient population with challenging work schedules and often with a propensity toward non-compliance. A noted limitation of this project was the inability to differentiate the rationale for indiscriminate HgbA1c monitoring. Reasons could include non-compliance by the patient or missed opportunity for consistent EBP. Another limitation is the lack of an electronic medical record for aggregation of patient data for ongoing analysis. Standout overall strengths of the project were the support of the clinic medical director and administrative staff and the availability of the raw data directly from the patient records.

Recommendations

Ongoing research is recommended in examining the continuity of care issues for the DM2 uninsured patients, as a vulnerable population, to ensure their full access to quality health care delivery. Care for this population is dependent on many variables which include not only an accessible health care home and medication resources but such parochial factors as transportation, convenient operational hours for shift workers, literacy assessments, and patient

education. These factors were mentioned throughout the research literature and were not the focus of this project but could be beneficial for future research projects when addressing the uninsured DM2 patient.

Dissemination

The research project was disseminated at the United Advanced Practice Registered Nurses of Georgia Annual State Conference 2016.

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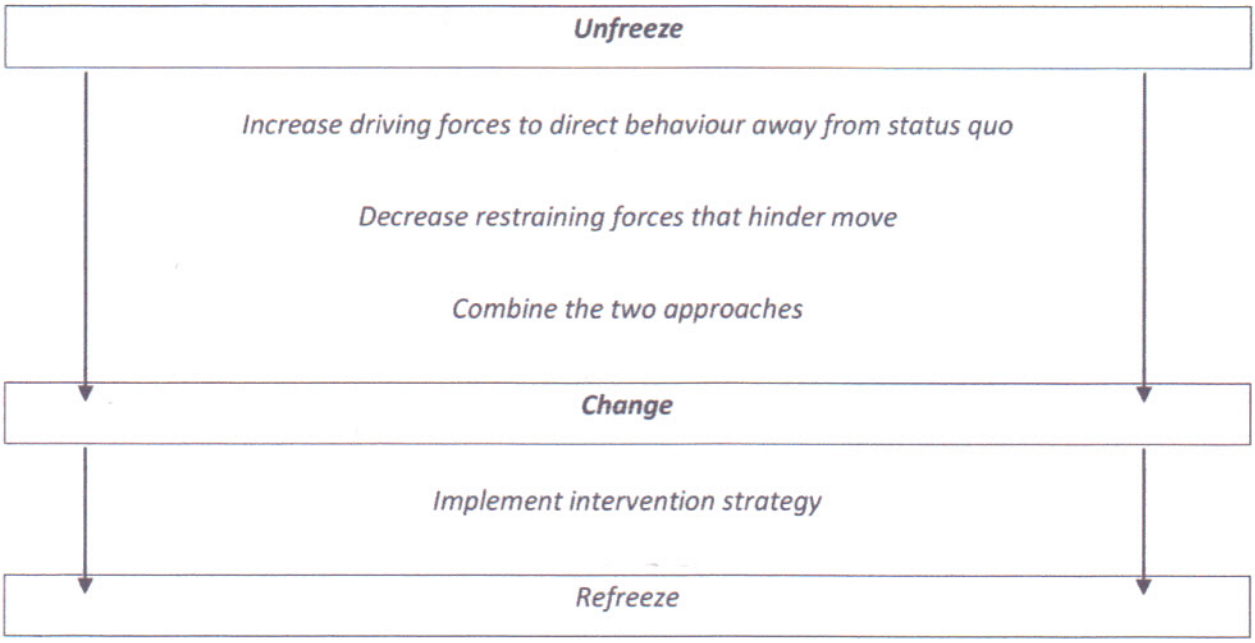
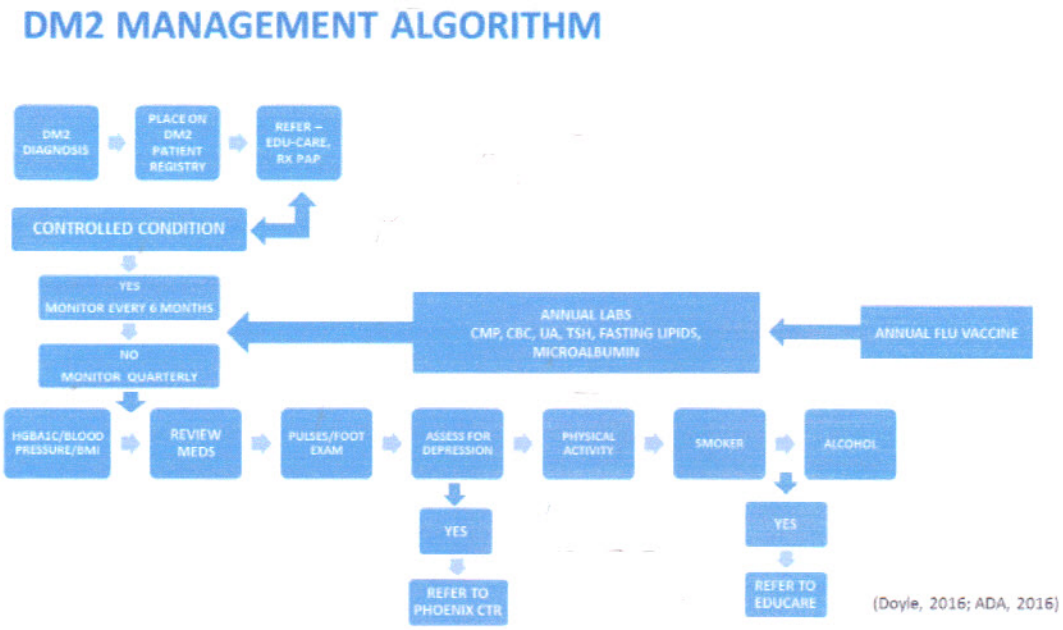
Appendix A

Kurt Lewin's Three Change Model for the Change Process (Swanson & Creed, 2014)



Appendix B


DM2 MANAGEMENT ALGORITHM
DM2 DIAGNOSIS
PLACE ON DM2 PATIENT REGISTRY
REFER – EDU-CARE, RX PAP
CONTROLLED CONDITION
YES
MONITOR EVERY 6 MONTHS
NO
MONITOR QUARTERLY
ANNUAL LABS
CMP, CBC, UA, TSH, FASTING LIPIDS, MICROALBUMIN
ANNUAL FLU VACCINE
HGBA1C/BLOOD PRESSURE/BMI
REVIEW MEDS
PULSES/FOOT EXAM
ASSESS FOR DEPRESSION
PHYSICAL ACTIVITY
SMOKER
ALCOHOL
YES
REFER TO PHOENIX CTR
YES
REFER TO EDUCARE
(Doyle, 2016; ADA, 2016)

Appendix C

DM2 PATIENT REGISTRY

PATIENT NAME_____ CLINIC #_____ FORM START DATE_____
FORM END DATE_____
*Note: Start new form every 12 months

PRESCRIPTION PATIENT ASSISTANCE PROGRAM YES_____ NO_____

PATIENT HAS ATTENDED EDUCARE FOR DIABETES EDUCATION YES_____ NO_____

RECURRING PREVENTIVE CARE Events (HgbA1c monitoring biannually if controlled condition or quarterly if not controlled.)

Date of Visit	Current DM2 Medication	Last HgbA1c result & date	Current Blood Pressure	Current Weight & BMI	Last Fasting Lipids result	Current Foot Exam/Pulses Checked	Assess for: Phys-Activity Depression Smoking/Alcohol	Next Scheduled HgbA1c

ANNUAL RECURRING EVENTS

Date of Visit	Labs: CMP, CBC, UA, Fasting Lipids, TSH, Microalbumin	Flu Vaccine	Last Dilated Retinal Exam		
	Date:	Date:	Date:		

(Doyle, 2016)

Appendix D

CHECKLIST – DATA EXTRACTION FORM

Patient Clinic Number_____ Cross Reference Number_____

ITEM	YES	NO	RESULT	COMMENT
DM2 Diagnosis Confirmed				
HgbA1c levels with dates			# >7% =	
Male				
Female				
Age 18-39				
Age 40-64				
African American				
Asian				
Caucasian				
Hispanic				
Income Limit-Members in household 1-8			Number of people in hh Total =	
Clinic Visit Dates			Total =	
Prescription History: Copy of 1 Rx				
PAP				

Note. Income Limit: 1=$20,240, 2=$27,380, 3=$34,340, 4=$41,300, 5=$48,260, 6=$55,220, 7=$62,180, 8=$69,140 (Houston Healthcare, 2016; Doyle, 2016; Shepherd et al., 2014)